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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,123	09/10/2003	George R. England	GC774-2	6906

7590 12/01/2005

VICTORIA L. BOYD
GENENCOR INTERNATIONAL, INC.
925 PAGE MILL ROAD
PALO ALTO, CA 94304-1013

EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,123	ENGLAND ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-32,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-32,34 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7-29-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 8-31-2005 are acknowledged. Claim 15 has been amended. Claims 1-4 and 33 have been canceled. Claims 34-35 have been added. Claims 15-32 and 33-35 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 7-29-2005 has been considered. An initialed copy is attached hereto.

Drawings

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Objections

Claim 15 is objected to because of the following informalities: Said claim contains an obvious grammatical error. It seems "a proteins" should read "a protein". Appropriate correction is required.

Claim Rejections Withdrawn

The rejection of claims 15-32 under 35 U.S.C. 112, second paragraph, as being indefinite by being dependent on multiple claims drawn to non-elected inventions is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 15-28, 31-32 and 34-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Fowler et al. (U.S. Patent 6,407,046) for the reasons set forth in the previous Office action in the rejection of claims 15-28 and 31-32.

Applicant argues:

1. Fowler et al. is not appropriate art as it fails to teach each and every element of the claimed invention.

2. Fowler et al. is not enabling.

3. The examiner's statement that the inducing feed composition is equivalent to the culture media disclosed in Fowler et al. since the specific components of said inducing feed composition are not recited is untenable.

4. Fowler et al. is silent on the addition of an inducing feed composition and also on the critical aspect on how they were able to induce protein production in the presence of glucose.

5. Example 2 of the instant specification shows that it is not the medium but the inducing feed composition that induces protein production when the cells are grown under otherwise identical conditions. Hence of skilled in the art would not have found the instant invention in the cited art.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant claims are drawn to methods of producing proteins (endogenous cellulase or heterologous proteins) utilizing a host cell wherein the said host cell can be a bacteria (*Bacillus, Streptomyces, Thermomonospora or Cellumonas*) or a filamentous fungus (*Trichoderma reesei*). Said host cell contains a vector wherein said vector can optionally comprise a sophorose or gentiobiose inducible promoter (*cbh* 1). Said methods contain one active step: "providing a host cell with an inducing feed composition" required for the accomplishment of the stated goal of the method (i.e. the production of a protein of interest). The "steps" recited with regard to the production of said inducing feed composition provided no descriptive limitations with regard to the composition of said inducing feed composition. Since the specification defines an inducing

feed as "a solution fed to a microorganism that causes or induces the production of the desired protein product" (see page 13 of the specification), any solution, including culture media, which results in the production of a desired protein meets the limitation of the claims. Moreover, the "steps" recited with regard to the production of said inducing feed composition are deemed to constitute a "product by process" description of the recited inducing feed composition. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As outlined previously, Fowler et al. disclose methods of recombinantly producing cellulases utilizing host cells comprising expression vectors wherein said host cells can be either bacterial, yeast or fungal. Fowler et al. further disclose that the bacterial host cells can be

Bacillus subtillis and the fungal host cells can be *Trichoderma reesei* (see column 6, lines 40-42). Moreover, Fowler et al. disclose that the expression vectors further comprise an inducible promoter and that said promoter can be cbh1 (see column 5, lines 54-60 and column 13, lines 51-53). Additionally, Fowler et al. disclose that the expressed protein can either be either homologous or heterologous to the host cell (see column 14, lines 24-25). While Fowler et al. do not explicitly disclose that the promoters used are sophorose or gentiobiose inducible; the disclosed *cbh1* promoter possesses these characteristics. Consequently, Fowler et al. anticipate all the limitations of the instant invention.

Claims 15-18, 23-29 and 34-35are rejected under 35 U.S.C. 102(e) as being anticipated by Lehmbeck (U.S. Patent 6,352,841) for the reasons set forth in the previous Office action in the rejection of claims 15-18 and 23-29.

Applicant argues:

1. Lehmbeck et al. is not appropriate art as it fails to teach each and every element of the claimed invention.

2. Lehmbeck et al. is not enabling.

3. The examiner's statement that the inducing feed composition is equivalent to the culture media disclosed in Lehmbeck et al. since the specific components of said inducing feed composition are not recited is untenable.

4. Lehmbeck et al. is silent on the addition of an inducing feed composition and also on the critical aspect on how they were able to induce protein production in the presence of glucose.

5. Example 2 of the instant specification shows that it is not the medium but the inducing feed composition that induces protein production when the cells are grown under otherwise identical conditions. Hence of skilled in the art would not have found the instant invention in the cited art.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant claims are drawn to methods of producing proteins (endogenous cellulase) utilizing a host cell wherein the said host cell can be a filamentous fungus (*Trichoderma reesei or Penicillium*) and said host cell contains a vector optionally comprising an inducible promoter.

Said methods contain one active step: "providing a host cell with an inducing feed composition" required for the accomplishment of the stated goal of the method (i.e. the production of a protein of interest). The "steps" recited with regard to the production of said inducing feed composition provided no descriptive limitations with regard to the composition of said inducing feed composition. Since the specification defines an inducing feed as "a solution fed to a microorganism that causes or induces the production of the desired protein product" (see page 13 of the specification), any solution, including culture media, which results in the production of a desired protein meets the limitation of the claims. Moreover, the "steps" recited with regard to the production of said inducing feed composition are deemed to constitute a "product by process" description of the recited inducing feed composition. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the

particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As outlined previously, Lehmbeck discloses methods of recombinantly producing cellulases utilizing fungal host cells. Lehmbeck further discloses that the fungal host cells can be *Trichoderma reesei* or a *Penicillium* species (see column 3, lines 23-32). Moreover, Lehmbeck discloses that the expression vectors further comprise an inducible promoter and that the expressed protein can be heterologous to the host cell (see column 3, lines 13-14). Consequently, Lehmbeck anticipates all the limitations of the instant invention.

Claims 15-28, 31-32 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchinson et al. (U.S. Patent 6,268,328) for the reasons set forth in the previous Office action in the rejection of claims 15-28 and 31-32.

Applicant argues:

1. Mitchinson et al. is not appropriate art as it fails to teach each and every element of the claimed invention.

2. Mitchinson et al. is not enabling.

3. The examiner's statement that the inducing feed composition is equivalent to the culture media disclosed in Mitchinson et al. since the specific components of said inducing feed composition are not recited is untenable.

4. Mitchinson et al. is silent on the addition of an inducing feed composition and also on the critical aspect on how they were able to induce protein production in the presence of glucose.

5. Example 2 of the instant specification shows that it is not the medium but the inducing feed composition that induces protein production when the cells are grown under otherwise identical conditions. Hence of skilled in the art would not have found the instant invention in the cited art.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant claims are drawn to methods of producing proteins (endogenous cellulase) utilizing a host cell wherein the said host cell can be a bacteria (*Bacillus, Streptomyces, Thermomonospora or Cellumonas*) or a filamentous fungus (*Trichoderma reesei*). Said host cell contains a vector wherein said vector can optionally comprise a sophorose or gentiobiose inducible promoter (*cbh* 1). Said methods contain one active step: "providing a host cell with an inducing feed composition" required for the accomplishment of the stated goal of the method (i.e. the production of a protein of interest). The "steps" recited with regard to the production of said inducing feed composition provided no descriptive limitations with regard to the composition of said inducing feed composition. Since the specification defines an inducing feed as "a solution fed to a microorganism that causes or induces the production of the desired protein product" (see page 13 of the specification), any solution, including culture media, which results

in the production of a desired protein meets the limitation of the claims. Moreover, the "steps" recited with regard to the production of said inducing feed composition are deemed to constitute a "product by process" description of the recited inducing feed composition. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As outlined previously, Mitchinson et al. disclose methods of recombinantly producing cellulases utilizing host cells comprising expression vectors wherein said host cells can be either bacterial, yeast or fungal. Mitchinson et al. further disclose that the bacterial host cells can be *Bacillus subtillis* and the fungal host cells can be *Trichoderma reesei* (see column 12, lines 14-15). Moreover, Mitchinson et al. disclose that the expression vectors further comprise an

inducible promoter and that said promoter can be cbh1 (see column 11, lines 38-39). Additionally, Mitchinson et al. disclose that the expressed protein can be heterologous to the host cell. While Mitchinson et al. do not explicitly disclose that the promoters used are sophorose or gentiobiose inducible; the disclosed *cbh1* promoter possesses these characteristics. Consequently, Mitchinson et al. anticipate all the limitations of the instant invention.

New Grounds of Rejection

35 USC § 112, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-32 and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The instant claims are drawn to methods of producing proteins (endogenous cellulase or heterologous proteins) utilizing a host cell wherein the said host cell can be a bacteria (*Bacillus, Streptomyces, Thermomonospora or Cellumonas*) or a filamentous fungus (*Trichoderma reesei*).

Said host cell contains a vector wherein said vector can optionally comprise a sophorose or gentiobiose inducible promoter (*cbh* 1). Said methods contain one active step: "providing a host cell with an inducing feed composition" required for the accomplishment of the stated goal of the method (i.e. the production of a protein of interest). The "steps" recited with regard to the production of said inducing feed composition provided no descriptive limitations with regard to the composition of said inducing feed composition. The specification is silent with regard to the specific components present in the inducing feed composition end-product. Moreover, the specification is silent as what times and temperatures are required to obtain an inducing feed composition with certain components. The specification defines inducing feed as "a solution fed to a microorganism that causes or induces the production of the desired protein product" (see page 13 of the specification); this is insufficient to meet the written description requirement.

The aforementioned claims are directed to encompass any solution fed to a microorganism that causes or induces the production of the desired protein product. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical composition of the encompassed compounds, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a

potential method for isolating it. The composition itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2datl966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel,* 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ROBERT A. ZEMAN
PATENT EXAMINER

November 22, 2005